



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10053, CMS-10302 and CMS-10468]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **August 29, 2016**:

ADDRESSES: When commenting on the proposed information collections, please reference the

document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at

<http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A))

requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Paid Feeding Assistants in Long-Term Care Facilities and Supporting Regulations; Use: In accordance with 42 CFR part 483, long-term care facilities are permitted to use paid feeding assistants to supplement the services of certified nurse aides. If facilities choose this option, feeding assistants must complete a training program. Nursing home providers are expected to maintain a record of all individuals used by the facility as paid feeding assistants. Form Number: CMS-10053 (OMB control number: 0938-0916); Frequency: Occasionally; Affected Public: Private Sector - Business or other for-profit and not-for-profit institutions; Number of Respondents: 4,250; Total Annual Responses: 4,250; Total Annual Hours: 25,500. (For policy questions regarding this collection contact Karen Tritz at 410-786-8021.)

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen Use: Section 182(b) of the Medicare Improvement of Patients and Providers Act (MIPPA) amended section 1861(t)(2)(B) of the Social Security Act (42 U.S.C. 1395x(t)(2)(B)) by adding at the end the following new sentence: ‘On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the

compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.’ We believe that the implementation of this statutory provision that compendia have a “publicly transparent process for evaluating therapies and for identifying potential conflicts of interests” is best accomplished by amending 42 CFR 414.930 to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.

All currently listed compendia will be required to comply with these provisions, as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. Form Number: CMS–10302 (OMB control number: 0938–1078); Frequency: Annually; Affected Public: Business and other for-profits and Not-for-profit institutions; Number of Respondents: 845; Total Annual Responses: 900; Total Annual Hours: 5,135. (For policy questions regarding this collection contact Cheryl Gilbreath at 410-786-5919.)

3. Type of Information Collection Request: Extension of a previously approved collection; Title of Information Collection: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment; Use: The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, expands access to health insurance for individuals and employees of small

businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP). The Exchanges, which became operational on January 1, 2014, enhanced competition in the health insurance market, expanded access to affordable health insurance for millions of Americans, and provided consumers with a place to easily compare and shop for health insurance coverage. The reporting requirements and data collection in Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment (CMS-2334-F) address: (1) standards related to notices, (2) procedures for the verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan; and (3) other eligibility and enrollment provisions to provide detail necessary for state implementation. Form Number: CMS-10468 (OMB control number: 0938-1207); Frequency: Annually; Affected Public: Individuals, Households and Private Sector; Number of Respondents: 13,200; Total Annual Responses: 13,200; Total Annual Hours: 8,899. (For policy questions regarding this collection contact Sarah Boehm at 301-492-4429.)

Dated: July 26, 2016

Martique Jones

Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

[FR Doc. 2016-17988 Filed: 7/28/2016 8:45 am; Publication Date: 7/29/2016]